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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,262	04/17/2002	Bruno Criere	017751-030	8894

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EXAMINER

CHANNA VAJJALA, LAKSHMI SARADA

ART UNIT PAPER NUMBER

1615

DATE MAILED: 01/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/030,262	<b>Applicant(s)</b> CRIERE ET AL.	
	<b>Examiner</b> Lakshmi S. Channavajjala	<b>Art Unit</b> 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 October 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7,9-12,14-35 and 47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7,9-12,14-35 and 47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>10-21-05</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Receipt of amendment, remarks, affidavit and IDS dated 10-21-05 is acknowledged.

Claims 13 and 36-46 have been canceled. Claims 1-7, 9-12, 14-35 and 47 are pending in the instant application.

### ***Response to Arguments***

Applicant's arguments filed 10-21-05 have been fully considered but they are not persuasive.

Applicants' state that as presented in the personal interview the claimed fenofibrate surprisingly yields greater bioavailability than the commercial embodiments of Curtet and Stamm patents, over which the claims have been rejected. It is stated that increased bioavailability of fenofibrate with a reduced dosage is important and that the present invention furthers the advances made by the commercial embodiments of Curtet and Stamm references. It is also stated that unlike Stamm teachings (which is an improvement over the fenofibrate or Curtet), instant invention achieves the same by increased percentage of fenofibrate and decreased percentage of the binder. Applicants refer to the Bobotas Declaration showing that the claimed formulation (ANTARA- a commercial embodiment) provides greater bioavailability on a per-milligram basis than the TRICOR formulations covered by the Curtet and Stamm patents and that the maximum daily dose of fenofibrate has been reduced from 300 mg or 200 mg (LIPIDIL or TRICOR) to 160 mg (instant). It is argued that neither the cited references teach or suggest that a combination of a higher percentage of fenofibrate and a lower

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percentage of a polymer to produce an increased bioavailability and a decrease on the amount of fenofibrate necessary for effective treatment. Applicants argue that the fenofibrate containing suspension of Stamm, sprayed on the neutral granule, is different from the claimed coated granules. Applicants state that the cited reference teaches away from the present invention because Stamm requires at least have 20% of the hydrophilic polymer and up to 50% fenofibrate as opposed to the 2-15% of binder and at least about 60%.

Applicants' arguments and the declaration of Dr. Bobotas have been considered but not found persuasive because Stamm and Curtet teach the claimed fenofibrate together with excipients required for the formulation such as binders. The difference between percentages of fenofibrate taught by Stamm is the percentage of fenofibrate and the percentage of the polymer claimed. While it is appreciated that the in vivo bioavailability of the fenofibrate containing commercial formulation (ANTARA of the present application) is shown to be higher than the bioavailability of TRICOR (commercial formulation of Stamm and Curtet), it is to be noted that the objective evidence of nonobviousness must be commensurate in scope with claims that evidence is offered to support. *In re Greenfield and DuPont* 197USPQ 227 (CCPA 1978); *In re Boesch and Slaney* 205 USPQ 215 (CCPA 1980); and *In re Tiffin and Erdman* 170 USPQ 88 (CCPA 1971). In the present application, the pending claims recite specific percentages of fenofibrate and a binding cellulose derivative, which components admittedly are taught by the prior art. The prior art cited differs from the claims only in the percentages. In order to show any unexpected bioavailability of fenofibrate, a proper

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comparison would be between compositions that are commensurate with the scope of the instant invention and that of the cited prior art that is outside the scope of the instant invention. In this case, a comparison was made between commercial formulations of the instant versus prior art formulations. However, the declaration describing commercial formulations do not describe the actual percentages of fenofibrate and the cellulose polymer present in formulations used. Accordingly, the increased and "unexpected" bioavailability seen with the commercial formulation ANTARA does not reflect the claimed percentages of fenofibrate and hydrophilic polymer. Therefore, in the absence of unexpected results that are commensurate with the scope of the instant claims, it is the position of the examiner that optimizing the percentage of fenofibrate and the excipients required for the bioavailability of fenofibrate would have been within the scope of a skilled artisan.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -6.30 PM

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lakshmi S Channavajjala  
Examiner  
Art Unit 1615  
January 6, 2006



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